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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,122	07/07/2003	Santu Bandyopadhyay	02506.00P600.1	7170

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NEW YORK, NY 10112

EXAMINER

SOROUGH, LAYLA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,122

Applicant(s)

BANDYOPADHYAY ET AL.

Examiner

Layla Soroush

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Priority

The Office Action is in response to the Preliminary Amendment filed July 7, 2003.

This application claims benefit of 60/393,750 07/08/2002. Claims 1-18 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 and 18 recite the limitation "percent inhibition." There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites no limitation toward percent inhibition of cells.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the "increase in the concentration and time duration of exposure." Claim 18 recites "wherein the percent inhibition is 85 to 100% with CA in about 3 days." With regards to the claim herein, it is unclear what is being inhibited. Therefore, the claim is rendered vague and indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of applicants admission.

Bandmpadhyay et al. ('118) teaches method for the treatment of Myeloid Leukemia (acute myeloid leukemia and chronic myeloid leukemia) in subjects such as animals, including human beings, which comprise administering to said subjects a pharmaceutical composition comprising an effective amount a betel leaf extract ('118; page 2 lines 25-29 and p. 3 lines 4-6), recited in claim 3. Betal extract contains the compounds chlorogenic acid (CA) and 3-o-p-Coumaryl (PCQ).

The reference further teaches that the effective amount of betel leaf extract is between 5 to 20 m/kg of body weight per day ('118; p. 3 line 25); and the composition may be administered upon alternate days for at least three weeks, preferably one month ('118; p. 3 line 27), meeting the limitation of claim 7. The compositions may further comprise additives including nutrients comprising proteins, carbohydrates, sugar, talc, magnesium stearate, cellulose, calcium carbonate, starch-gelatin paste and/or pharmaceutically acceptable carriers ('118; p. 3 line 10-15)," as recited in claim 4. The routes by which the compositions may be administered are "orally or intramuscularly" ('118; p. 3 line 16), recited in claim 6.

Bandmpadhyay et al. ('118) does not expressively teach the extract components chlorogenic acid (CA) or 3-o-p-coumaryl quinic acid (PCQ). Additionally, the prior art reference does not specifically teach the ratio of CA and PCQ (recited in claim 5) nor

the percentage growth inhibition of Erythroleukemia cells, promonocyte cells, and CML's leukemic cells, as recited in claims 8-18.

However, the prior art reference teaches that the extracts are from the same source as used by applicant and that the extracts have the same efficacy of treating myeloid leukemia. Also, the observation of the specific inhibition percentages that would have resulted from practicing the methods taught by Bandyopadhyay ('118) is a matter that does not impart patentable moment to the claimed subject matter. One of ordinary skill in the art, by virtue of the very teaching that the compounds are effective for the treatment of myeloid leukemia, would have been imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree and the determination of the percentage inhibition for the compounds would have been a matter well within the purview of the skilled artisan.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of Zon et al. (US Pat. No. 5700927) and Bandyopadhyay et al. (U.S. Patent Application Publication No. 2003/0229140)

Bandmpadhyay et al. ('118) is as discussed above.

Bandmpadhyay et al. ('118) does not expressively teach the extract components chlorogenic acid (CA) or 3-o-p-coumaryl quinic acid (PCQ). Additionally, the prior art reference does not specifically teach the ratio of CA and PCQ (recited in claim 5) nor the percentage growth inhibition of Erythroleukemia cells, promonocyte cells, and CML's leukemic cells, as recited in claims 8-18.

In the Background of the Invention, Zon et al. teaches the relationship between erythroleukemia and promonocytes (see column 1 and 2).

Additionally, Bandyopadhyay et al. ('140) teaches a pharmaceutical composition useful for treating chronic myeloid leukemia comprising chlorogenic acid and/or 3-o-p-coumaryl quinic acid, i.e., the latter being a chlorogenic acid analog, in an amount of from 1 and 50 mg per kg body weight/day, wherein the chlorogenic analog may be obtained either from natural or synthetic sources, wherein the composition may contain various additives of the type claimed, wherein the composition may be administered through oral, intravenous, intramuscular or subcutaneous routes and wherein the composition may be administered for a period ranging from four to twelve weeks (page 2, sections (0027 - 0032)). suitable for oral administration (col. 9, line 66 - col. 10, line 25).

The prior art reference teaches that the extracts are from the same source as used by applicant and that the extracts have the same efficacy of treating myeloid leukemia. Further, the relationship between the cells affected by myeloid leukemia is taught by the Zon et al. reference. Therefore, the observation of the specific inhibition percentages that would have resulted from practicing the methods taught by Bandyopadhyay ('118) is a matter that does not impart patentable moment to the claimed subject matter. One of ordinary skill in the art, by virtue of the very teaching that the compounds are effective for the treatment of myeloid leukemia, would have been imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree and the determination

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of the percentage inhibition for the compounds would have been a matter well within the purview of the skilled artisan. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Badmpadhyay et al. compound by routine experimentation (see 2144.05 11) because the prior art teaches the same composition in treatment of myeloid leukemia. The motivation to optimize the dose range of the Badmpadhyay et al. final formulation is because he would have had a reasonable expectation of success in achieving the safest clinical outcome in treating patients with myeloid leukemia.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 6, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Patent No. 7,045,157 and claims 21-22, 24-25, and 28 of co-pending application no. 11/222815. Although the conflicting claims are not identical, they are not patentably distinct from each other because: the Patent claims entitle a method differently than here, i.e., "method of inducing and assaying IFN γ production" and "use of betel leaf extract or a composition comprising effective amount of betel leaf extract for inducing IFN- γ from human peripheral blood mononuclear cells or as a Th1 type immunomodulator" in the patent claims and copending claims vs. "for treating chronic myeloid leukemia" in the present claims. However, Dunussi-Joannopoulos et al. teaches Th1 cells secrete IL-2 and IFN- γ induce cellular immune responses useful in immunotherapies for AML. The patent and co-pending claims do not expressly require chlorogenic acid and 3-o-p-Coumaryl quinic acid as is required in the present claims. However, the patent and co-pending claims require a betel leaf extract which contain both chlorogenic acid and 3-o-p-Coumaryl quinic acid.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of Patent No. 6852344. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both the current and patent claims encompass the treatment of chronic myeloid leukemia and there is substantial overlap with regard to the type of leukemia being treated. The patented claims do not expressly require

chlorogenic acid as is required in the present claims. However, the patent claims require a betel leaf extract which contain both chlorogenic acid and 3-o-p-Coumaryl quinic acid.

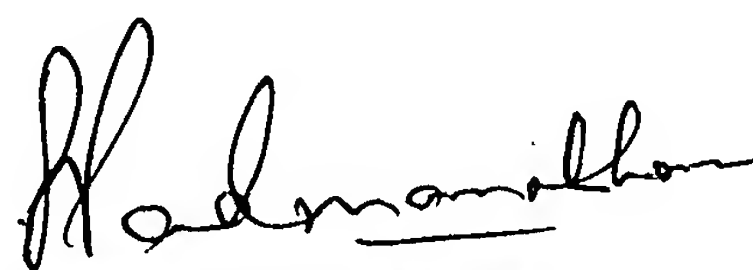
Claims 1, 4, 6, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 31, and 32 of Application No. 10/338689 and claims 24, 26, 28-29 and 30 of Application No. 11/174545. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both the current and co-pending claims encompass the treatment of chronic myeloid leukemia and there is substantial overlap with regard to the type of leukemia being treated. The copending claims do not expressly require betel leaf extract as is required in the present claims. However, the copending claims require chlorogenic acid a betel leaf extract.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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